GPS CAPABILITIES PROFILE

computer validation

Your quality computer validation team

Applying the PMA and GAMP 5 Models to Computer Systems Validation

Computer Validation Excellence
We offer an effective blend of computer related systems (CRS) validation, quality software development auditing, cGMP compliance in automated systems, and 21 CFR Part 11 services, achieving excellence unparalleled in the industry. Our rich experience in computer systems in GMP applications dates back over 25 years. Our people are the simple key to the excellence, dedication, experience and skill that will make your computer validation project a real success.

Computer Validation Experience
Our experience includes Programmable Logic Controllers (PLC), Distributed Control Systems (DCS), and Personal Computer (PC) applications. Our experience includes many of the most popular computer systems, large and small. From simple relay replacements to critical application control, from local to networked control, we have experience you can trust.

New Systems
At GPS we believe that in order to validate a computer system, it must first be understood. If you are dealing with a new or obscure system, or a one–of–its–kind custom engineered system, our engineers and scientists will tackle the challenge with aggressive, refined learning skills. With that foundation, we will build a successful validation project.

How Do We Do It?
We apply the generally accepted PMA (the former Pharmaceutical Manufacturer's Association) model for computer validation or GAMP 5, as you prefer. These models are life cycle approaches endorsed by industry, vendors, and the Food and Drug Administration (FDA). They can be confusing, hard to understand and even harder to apply to your specific project. Let us help your staff break through the confusing world of validation steps and terminology.

Process Integration
Our knowledge of process control and cGMP requirements brings depth to our computer validation work which is missing from our competition. We work with the end product requirements and the FDA's viewpoint in mind. For example, we know how to validate critical alarms and process tuning which could impact final product quality.

What If You Started Too Late?
If your system was not designed with validation in mind, we will determine your validation options and propose solutions.

Support Services and Part 11
We write computer system standard operating procedures (SOP's) to control computer related systems, equipment and processes without making compliance a nightmare. We write or revise functional requirements, audit computer system vendors, write system specifications, develop structural and functional test plans, conduct Part 11 analysis, and more.

Fearless Quality
If computer validation makes you tremble, why not turn to the experts at GPS? We can give you the support, the professional service, and the dedication to high quality validation which assures success.

Act Today
Call today to discuss your computer validation project!

1-800-700-5147

At a Glance

Service: *Computer Validation*
Compliance: *21CFR Part 211*
Capability: *PLC, DCS, PC*
Best at: *High Quality Validation*
Project Scope: *Full or Partial*
Contact: *Blair Conley*
Sales: **1-800-700-5147**